UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	**CASE NO. 1:14-CV-01748** **MDL 2545** **JUDGE MATTHEW F. KENNELLY** **This Document Relates to:** ***Konrad* v. *AbbVie*,** **Case No. 1:15-cv-00966**

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR ALTERNATIVELY FOR A NEW TRIAL OR REMITTITUR

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PRELIMINARY STATEMENT

Plaintiff's opposition fails to identify substantial evidence in any of the several areas where the verdict is unsupported. His experts' opinions on case-specific causation remain facially inadequate under the Court's instructions and unsupported even by the studies that the experts featured in their testimony at trial. And Plaintiff's efforts to fill this gap with other evidence fail as a matter of law (because causation can be established only through expert testimony) and as a matter of fact (because none of the other evidence is tied to Mr. Konrad). Without causation, the entire case fails. Nor can Plaintiff find a path to save his negligence claim. That claim is still squarely blocked by the FDA's precisely focused review of the science at the time Plaintiff was warned in 2010, by Dr. Pence's own admissions about the label, and by Dr. Overby's clear testimony as a learned intermediary that he understood TRT may increase CV risk. The testimony of Plaintiff's own experts likewise remains fatal to his misrepresentation and concealment claims. Dr. Kessler outright conceded that the branded Patient Brochure and the "Shadow Ad" contained no false statement of fact. His alternative opinion—that the Shadow Ad "implied" a symptom benefit—is legally insufficient. The opinion is immaterial as well, inasmuch as symptomatic benefits were stated explicitly in the approved label and in the Patient Brochure (with which Dr. Kessler did not take issue). Finally, the record of disclosures to the FDA and its approval of AndroGel labels remains dispositive of Plaintiff's fraudulent concealment claims. There is simply no evidence or even a claim that science was concealed from the FDA, which found that AndroGel labels contained "adequate" information every time a label was approved.

If this Court does not enter judgment for AbbVie, it should grant AbbVie's motion for a new trial. Plaintiff fails to resolve the inconsistency between the verdicts on strict liability and negligence. Both claims required identically-defined proof that AndroGel was unreasonably dangerous and that AndroGel caused Plaintiff's heart attack. Yet the jury's verdict on strict liability found at least one of these requirements unmet, while its verdict on negligence differently found

that both had been proven. And despite Plaintiff's suggestions otherwise, it is well established that the remedy for an irreconcilable inconsistency is a new trial on all claims.

In the event that the Court neither enters judgment for AbbVie nor grants a new trial, it should bring the punitive damages award into compliance with the Constitution and Illinois law. The Constitution permits few awards exceeding a *single digit* ratio, and Plaintiff fails to address controlling precedent that cases like this should be further limited to a 1:1 ratio. Nor does this case remotely involve "reprehensible" conduct. AbbVie acted appropriately at all times, as confirmed by its interactions with the FDA. There is no evidence that it concealed any science from the FDA. AbbVie's advertising was well-known to the FDA, reviewed when appropriate, and never the subject of any FDA action during the period at issue. While AbbVie at times disagreed with the FDA, it was transparent about its position. Even today, the FDA never has found that AbbVie did not comply with its instructions or rules. And science still has not shown that TRT increases the risk of major CV events. The punitive damages award merely confirms that Plaintiff succeeded in inflaming the jury with views of science and AbbVie's marketing activities that exist only inside the courtroom. And they were improperly provoked to punish AbbVie, not for its conduct with respect to Mr. Konrad, but for the 15-year history of marketing AndroGel. That provocation flouts the Supreme Court's clear instructions.

ARGUMENT

I.
THE VERDICT WAS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE

A. PLAINTIFF FAILED TO PROVE BUT-FOR CAUSATION

Plaintiff failed to present substantial evidence of but-for causation because: (1) Dr. Cuculich never testified that, but for using AndroGel, Plaintiff would not have had a heart attack; (2) Dr. Cuculich conceded that it was impossible for Plaintiff to have used AndroGel at the prescribed dose; and (3) Dr. Ardehali admitted that none of the epidemiological evidence on which he relied contained findings specific to Plaintiff's age or irregular AndroGel usage pattern. (Mot.

3.) Plaintiff is unable to rebut any of these critical failures of proof. (*See* Opp. 5-8.)

Plaintiff claims he had to prove only that AndroGel "directly contributed" to his injury. (Opp. 5.) Yet the Court's instruction clearly states otherwise: "AbbVie's product or conduct was a cause in fact of Plaintiff's heart attack if it directly contributed to his heart attack ***and*** without it his heart attack would not have occurred." (ECF 109 at 18 (emphasis added).) Plaintiff therefore had to present substantial evidence meeting both of these standards. Plaintiff cites Dr. Cuculich's testimony about the amount of plaque in Plaintiff's arteries and about potential alternative causes (Opp. 5-6), but that testimony goes only to the "directly contributed" standard because none of it identifies AndroGel as the necessary factor that caused Plaintiff to have a heart attack.[1] Plaintiff's argument that Dr. Cuculich need not use the phrase "but-for" (Opp. 6) misses the point. The point is not language but substance, and Dr. Cuculich simply did not opine that Plaintiff's "heart attack would not have occurred" without AndroGel. Plaintiff's failure to elicit that seemingly straightforward testimony is fatal to his claims.

Plaintiff tries to fill the gaps in Dr. Cuculich's testimony with general causation evidence (Opp. 7), but he never ties that evidence to the specific facts of his own case. He cites studies finding increased CV risk from TRT use,[2] but his own minimal exposure to AndroGel places him well outside the population covered by those studies. Plaintiff tries to solve this problem by citing his own testimony that he used the drug every day for eight weeks, but no reasonable jury could have believed that testimony in light of (i) Plaintiff's admission that a 30-day supply could not have lasted him 50 days, and (ii) Dr. Cuculich's confirmation that it was physically impossible for

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1 Nor can Plaintiff rely on Dr. Cuculich's testimony that AndroGel was a "substantial factor" in bringing about the heart attack to satisfy his burden on cause in fact. Under the instructions, "substantial factor" goes to proximate cause, not cause in fact. (Opp. 6 n.2; ECF 109 at 18.)

2 Plaintiff's reliance on Dr. Ardehali's misinterpretation of the AndroGel clinical trial data (which was uncontestably debunked by Dr. Khera (Tr. 2845:24-2848:20)) does not solve this problem. That study made no findings of risk from exposures under 90 days. And *no subjects in the study had a heart attack*. (Tr. Exs. 3053, 3080; Tr. 1548:24-1549:9.) Evidence that testosterone or estradiol levels increased in the study is immaterial for the same reason and because Plaintiff presented no evidence that his own testosterone or estradiol levels increased when he was exposed to the drug.

Plaintiff to have used AndroGel at the prescribed dose. (Tr. 1627:4-22; 1800:13-1802:17.) Even e weeks of use would not put him in any of the groups where studies have found an increased risk.

B. PLAINTIFF FAILED TO PROVE NEGLIGENCE

The Court instructed the jury that Plaintiff's strict liability and negligence claims required proof of both unreasonable danger and causation. (ECF 109, at 12-13.) The instructions also were clear that the "unreasonably dangerous" standard could not be met if AbbVie's warnings were adequate. (*Id.* at 15.) The jury returned a verdict for AbbVie on Plaintiff's strict liability claim, reflecting Plaintiff's failure to prove either or both of unreasonable danger and causation (*see infra* § II.A). The record shows that neither of the two requirements was supported by sufficient evidence, and this is fatal to Plaintiff's negligence claim as well.

1. Plaintiff Failed to Prove Unreasonable Danger

It is undisputed that the FDA repeatedly examined the scientific evidence of CV risk from TRT, including an extensive review conducted almost precisely when Plaintiff was prescribed AndroGel. The FDA determined as late as May 2013 that there was no CV safety issue, and no need was found for any change to the warnings until 2015. (*See* Mot. 5-6 & n.8.)

In response, Plaintiff contends that all of the FDA's actions were predicated on its view that the AndroGel indication was confined to classical hypogonadism. (*See* Opp. 9.) But there was no evidence that any of the FDA's scientific assessments of risk were based on the distinction between classical and non-classical patients. Indeed, (1) there was no evidence that the cause of a patient's hypogonadism is associated with increased CV risk; (2) Dr. Ardehali was barred from testifying to such an opinion because no such evidence exists to support it (*e.g.*, CMO 46, at 35), and (3) Dr. Pence herself admitted that the FDA made no distinction between men who had classical vs. non-classical hypogonadism in its review of the Basaria study in May 2010, when Plaintiff was prescribed AndroGel (Tr. 2472:22-2473:6). Accordingly, FDA's approval of AndroGel's label disproves Plaintiff's claim that the label's warnings were inadequate.

Dr. Pence also admitted that the labeling in 2010 already contained a warning of potential heart attack risk. (Mot. 6.) Plaintiff argues otherwise, pointing out that the label did not literally contain the phrase "heart attack" (Opp. 8), but Dr. Pence admitted that the warning about "thromboembolic events" was *broader* and encompassed heart attacks as well as other CV events. (Tr. at 2443:13-2444:7.) This testimony also undercuts Plaintiff's reliance on Dr. Pence's opinion that adverse event reports would have justified adding the CV risk warning in 2007. The broader thromboembolic event warning was added in 2009, before Plaintiff's injury in 2010.[3]

Plaintiff's failure-to-test theory does not solve these problems. As the instructions stated, Plaintiff cannot recover for "failure to test" without proving that AndroGel was unreasonably dangerous, that AndroGel had inadequate warnings, and that those inadequate warnings caused Plaintiff's injury. (*See* ECF 109, at 13.) Accordingly, any so-called "failure to test" theory suffers from the same evidentiary deficiencies as the failure-to-warn claim that subsumes it. In all events, Plaintiff's contention that AbbVie marketed AndroGel to a larger group of men than it was tested for (Opp. 10) is entirely irrelevant, as nothing in the record suggests that the scope of the indication constrains the scope of monitoring for and detecting a post-marketing safety signal, which in turn drives warnings. (*See* Tr. 632:9-18; 1454:25-1455:5, 1485:16-1486:19, 1567:7-13, 2344:22-24, 2999:3-3000:3.) Rather, the consistent testimony—from both sides—is that adverse events are scrutinized for their relationship to use of the product, period. (*E.g.*, Tr. 1460:12-1461:6, 2351:1-15.) Etiology of hypogonadism is simply not a criterion for safety assessments. Moreover, Dr. Ardehali conceded that the FDA knew about all of the epidemiological science, mechanism studies, and MedWatch forms that he relied upon for his warnings opinions. (Tr. 1489:2-1491:6, 1492:17-1493:7, 1494:1-11.)[4]

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[3] *See also* Tr. at 2457:1-2458:20 (Dr. Pence admitting that the company and FDA could not find a safety signal as of April 2008); Tr. at 2477:20-2478:17 (admitting that, even after Plaintiff's heart attack, AbbVie and the FDA agreed the label was adequate and AndroGel did not increase CV risk).

[4] The same record demonstrates Plaintiff's failure to present sufficient evidence that AbbVie had a duty to conduct a long-term, placebo-controlled trial before seeking FDA approval, or to run a large CV safety study until 2015. Here, too, it is undisputed that long term safety studies are not done routinely and are triggered by confirmation of a

2. Plaintiff Failed to Prove Causation

Tennessee's independent knowledge doctrine bars any finding of causation in this case because Dr. Overby independently believed at the time of Plaintiff's prescription that AndroGel may increase the risk of heart attack. (Mot. 6.) Plaintiff argues that Dr. Overby's understanding was limited to the hematocrit mechanism. (Opp. 9-10.) This misses the point yet again: The question is whether he believed that there was a potential CV risk and that a warning could be given to the patient. The record confirms that Dr. Overby did in fact have such an understanding. What the mechanism might be adds nothing to the analysis, because doctors advise patients based on risk and benefit, not theoretical mechanisms.[5] Nor does Plaintiff's further reliance on the Court's earlier ruling that the learned intermediary doctrine did not warrant summary judgment come to grips with the independent knowledge doctrine. The independent knowledge doctrine focuses exclusively on whether Dr. Overby *knew* of the risk of Plaintiff's injury.[6] He did.[7]

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safety signal. (Trial Ex. 3094; Tr. 632:9-18, 1487:10-13, 1567:7-13; 2812:23-2813:5, 2999:3-3000:9.) Plaintiff's further contention that Mr. Wojtanowski and Mr. Miller admitted that AbbVie conducted "no testing for safety and efficacy in age-related men" is misleading and inapposite. It is misleading in that Mr. Miller stated only that no large-scale CV risk study was conducted (as opposed to safety being tested in men with age-associated hypogonadism, which was done), and Mr. Wojtanowski stated only that the trials were not placebo-controlled. (Opp. 10.) It is inapposite because Mr. Miller's sole relevant testimony on the duty to test was that CV safety studies are not done routinely, and that the CV studies discussed in his slide presentation were predicated not on a safety signal but on a concern that TRTs were being stigmatized and may actually have cardiovascular benefit. (Tr. 1158:1-19, 1184:12-1187:21)

5 Plaintiff suggests that the label instruction to monitor hematocrit was insufficient because other potential mechanisms by which AndroGel might cause a heart attack were not explicitly mentioned in the label. (Opp. 9-10.) But Plaintiff concedes that those other mechanisms cannot be monitored. (*Id.*) Telling doctors to look out for mechanisms that cannot be observed makes absolutely no sense. Notably, Plaintiff's evidence was that the 2015 label change concerning potential CV risk should have been made earlier. But that change says nothing about mechanisms. (*See* Trial Ex. 3270.7.)

6 *See, e.g.*, *Collins* v. *Danek Med., Inc.*, 1999 WL 644813, at *9 (W.D. Tenn. Mar. 23, 1999) ("[B]ecause Dr. Wood was independently aware of all of the risks and dangers of the Luque device, any alleged failure to warn was not the proximate cause of Collins' injury."); *Harden* v. *Danek Med., Inc.*, 985 S.W.2d 449, 452 (Tenn. Ct. App. 1998) (granting summary judgment for defendant when plaintiff's doctor "was fully aware of the risks involved [and] did not rely upon certain literature distributed or sponsored by the defendant in making his determinations" because "defendant's alleged failure to warn plaintiff is not considered to be the proximate cause of plaintiff's injury under this doctrine").

7 Nor does the record show that, if he had been told of the potential increased risk of heart attack, Plaintiff would have decided to act against Dr. Overby's recommendation that he take AndroGel (*see* Tr. 1602:25-1603:4 (Q. "[Y]ou trusted him to weigh the risks and benefits of medications before prescribing them to you, right?" A: "Yes."); 1621:4-20 (testifying that he believed safety information in the label was "for my doctor," so he did not read it); *see also* (Overby Test. Tr., Ex. 1, 138:18-139:17; *id.* 197:8-21 (Dr. Overby testifying that he warned patients of heart attack risk in 2010); Tr.1626:22-24.)

C. PLAINTIFF FAILED TO PROVE HIS MISREPRESENTATION CLAIM

Plaintiff also failed to present substantial evidence that (1) AbbVie made a false statement of material fact, or (2) Plaintiff and/or his physician Dr. Overby justifiably relied on any such statement. (Mot. 7-10.) Again, Plaintiff has no answer to these critical failures of proof.

Plaintiff cites a wide range of testimony purportedly showing misrepresentations, but the only relevant statements for purposes of this case are ones that Plaintiff himself actually saw. At trial, Plaintiff testified that he saw two pieces of advertising: a branded brochure he received from Dr. Overby (Trial Ex. 2000.) and the unbranded television commercial known at trial as the "Shadow Ad."[8] (Trial Ex. 209.1.) Dr. Kessler admitted that neither of these materials contained a false statement and that their contents were consistent with applicable labeling at the time. (*E.g.* Tr. 881:2-9.) Dr. Kessler could offer only an alternative opinion that the Shadow Ad was misleading because it discussed "implied health benefits" but omitted risk information.[9] (Tr. 813:3-9, 815:7-13.) This testimony is insufficient as a matter of law. The law requires a false statement of fact, not merely an allegedly misleading implication. And, in this case, the allegedly misleading implication is significant only for regulatory purposes, *i.e.*, that, under FDA regulations, statements of product benefits must be accompanied by risk information (which does not apply for disease awareness ads). Any violation of such a regulation is irrelevant under the Court's instructions. (*See* ECF 109, at 19 (FDA instruction); Mot. 18.)

Plaintiff offers the theory that mentioning symptomatic improvement in advertisements amounts to a false statement because AbbVie did not study this in men with age-related hypogonadism. This theory is directly contradicted by the clinical trial documents, the FDA-approved text in the AndroGel 1% label which describes the findings of symptom improvement

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[8] Plaintiff's opposition cites four documents that purportedly contain false statements. (Opp. 13.; Opp. Exs. 6-9.) But of the four documents he cites, he received only one (the AndroGel brochure), and therefore cannot demonstrate that he relied on the other three.

[9] To the extent that Plaintiff relies on Dr. Kessler's testimony that the Shadow Ad contained falsehoods because it "omitted the approved indication," (Opp. 13.) Plaintiff cannot contend that his knowledge of the indication would have changed his decision to use AndroGel when he received the full AndroGel label at the time of his prescription. (Trial Ex. 2000.)

(including in patients with age-related hypogonadism), the FDA's review of ad content describing symptom improvement in 2000 (which content carried through 2010), and Dr. Kessler's admission that he had no problem with the patient brochure provided to Mr. Konrad, which again described symptom improvement benefits. (Tr. 881:2-9; Tr. Exs. 2000.3-5, 3049.130-131, 3050, 3148.10).[10]

Plaintiff argues that Dr. Overby's "overwhelming exposure" to marketing materials, in addition to his "specific actions" of purportedly prescribing AndroGel to treat fatigue, effectively amounts to reliance. (Opp. 14.) This argument conflates exposure and reliance. Exposure to statements is not reliance on them. And Dr. Overby specifically disclaimed any reliance on marketing materials, let alone reliance on any purportedly false statements contained therein, in deciding to prescribe AndroGel to treat Mr. Konrad's hypogonadism. (Mot. 10.)

Nor could a reasonable jury have found for Plaintiff on his new theory that Dr. Overby treated him for fatigue because it was "a symptom that AbbVie targeted" in its marketing. (Opp. 13-14.) Dr. Overby's testimony and medical records undisputedly demonstrated: (1) he conducted a full workup of Plaintiff's symptoms and complaints (Mot. 10); (2) he diagnosed Plaintiff with secondary hypogonadism and prescribed AndroGel for that purpose (Mot. 9); and (3) he tested Plaintiff for elevated clotting risk before finally deciding to prescribe AndroGel (Tr. 1588:2-9).

D. PLAINTIFF FAILED TO PROVE FRAUDULENT CONCEALMENT

AbbVie's initial brief demonstrated that Plaintiff could not point to any material omission that he or his physician relied upon, and thus failed to present substantial evidence to support fraudulent concealment. (Mot. 11-12.) Plaintiff concedes that AbbVie's representations to the

[10] Plaintiff speculates that the jury could have concluded that AbbVie's alleged off-label promotion to men falsely implies that AndroGel has been proven safe or effective for men with age-related hypogonadism. (Opp. 11-13.) Yet none of AbbVie's marketing materials actually stated that AndroGel is safe and effective for men with age-related hypogonadism. And "implications" are not misrepresentations under the instructions and were not substantiated in fact. Plaintiff also does not respond to AbbVie's argument that additional information on age-related hypogonadism would not have changed his decision to use AndroGel, given the undisputed fact that Plaintiff was never diagnosed with age-related hypogonadism, and he presented no evidence that he should be included in that category of patients. (Mot. 9, 12.) Plaintiff's further argument that marketing materials claiming AndroGel was safe were false because AbbVie did not conduct "a [placebo]-controlled study to evaluate [] long-term safety" (Opp. 11-12) is meritless because the FDA repeatedly concluded that the clinical trials were sufficient to prove safety and efficacy, without the need for a long-term safety trial. (*See supra* § B.1.)

FDA were not deceptive, but tries to distinguish AbbVie's representations to patients and doctors. (Opp. 14-15.) Plaintiff fails, however, to identify any statement to patients and doctors that was not also made to the FDA. Moreover, Plaintiff ignores the elephant in the room on disclosure: the AndroGel label itself discloses information on risk, benefit, and clinical testing (as well as the indication itself). Since 2000, FDA has approved this disclosure, including the testing data, as adequate. (Trial Ex. 3046.) Plaintiff identified no material omissions from the AndroGel labeling or medication guide that he received. Nor could he have relied on any such omission because he never read the label. As to disclosures in advertising, Dr. Kessler conceded that AbbVie's marketing too was consistent with the FDA-approved label.[11] (*See* Mot. 8-9.) Plaintiff provides no response to AbbVie's other points that he failed to prove the reliance and causation elements of fraudulent concealment.

II.
ALTERNATIVELY, THE COURT SHOULD ORDER A NEW TRIAL

A. PLAINTIFF FAILS TO RECONCILE THE VERDICTS ON STRICT LIABILITY AND NEGLIGENCE

Plaintiff argues that the verdicts can be reconciled because strict liability "focuses on" the product, whereas negligence "focuses on" AbbVie's conduct, and because causation means something different for each claim. (Opp. 16.) Plaintiff is wrong. Regardless of what the tortious-conduct element of each claims "focuses on," the causation question is always the same—*viz.*, whether AndroGel caused Plaintiff's heart attack. Indeed, the jury was given the exact same causation instruction for all of Plaintiff's claims. (ECF 109, at 18). Likewise, the Court gave the

[11] This also disposes of Plaintiff's argument that AbbVie concealed important safety information from patients and doctors because the Shadow Ad allegedly omitted certain points about risk. It simply did not need to, because both Mr. Konrad and Dr. Overby received the label itself, the Med Guide, and the patient brochure (which repeatedly told the reader to read the label). (Tr. 1494:8-11, 1495:9-11, 2442:21-2443:25, 2477:20-2478:17.)

Plaintiff's argument that changes to the 2015 AndroGel label prove that the label Plaintiff received in 2010 purposely omitted material facts about CV safety and age-related hypogonadism is contrary to the law (which predicates liability on what was known and reasonably knowable at the time) and to the undisputed facts, which established the FDA's repeated conclusions that the label adequately reflected the scientific evidence available at the time. (Mot. 11.) No possible signal emerged either for the FDA or from AbbVie until years after the events at issue in this case.

same instruction on "unreasonably dangerous" for both the negligence and strict liability claims. Accordingly, the only remaining question is whether the jury could have found that all of the elements of negligence were met, including unreasonable danger and cause in fact, but still could have found that the elements of strict liability were not.[12] The answer is clearly no. A simple syllogism demonstrates the inconsistency:

1. As just discussed, both the negligence claim and the strict liability claim required Plaintiff to prove that (1) "AndroGel was unreasonably dangerous" and (2) "AbbVie's product or conduct was a cause in fact and legal cause of Mr. Konrad's heart attack." (ECF No. 109 at 12–13; *see id.* at 15, 18 (defining elements identically for both claims)).
2. The "unreasonably dangerous" and "causation" elements were the only strict liability elements disputed at trial.[13]
3. Thus, in finding against Plaintiff on his strict liability claim, the jury necessarily concluded that one or both of these elements was not met, and yet in finding for Plaintiff on his negligence claim, the jury necessarily concluded that both elements were satisfied.

The jury's inconsistent conclusions on these identically defined elements thus cannot be reconciled.

Plaintiff's reliance on *Connelly* v. *Hyundai Motor Co.*, 351 F.3d 535, 542 (1st Cir. 2003)—a wrongful death case under New Hampshire law, where a jury found a car manufacturer liable for negligence but not for strict liability—is misplaced. In that case, the Court examined the elements of each claim and found significant differences between them. The Court specifically noted that, unlike the strict liability claim, the negligence claim did not require plaintiff to prove a design defect, and that a design defect was defined differently under the two claims. *Id.* at 541. The many

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[12] *See, e.g.*, *Van Stan* v. *Fancy Colours & Co.*, 125 F.3d 563, 571 (7th Cir. 1997) (no inconsistency where "[d]ifferent elements make up" the claims); *Sizer* v. *Rossi Contractors*, 2002 WL 1559694, at *4 (N.D. Ill. July 16, 2002) (no inconsistency between claims with "distinct elements," as jurors "could have found plaintiff established the elements of an emotional distress claim, but not the elements of a discrimination claim"); *Frain* v. *Andy Frain, Inc.*, 660 F. Supp. 97, 99 (N.D. Ill. 1987) (inconsistency after comparison and analysis of respective elements).

[13] Plaintiff suggests it is "self-serving[]" for AbbVie to note that these were the only disputed elements so that the jury verdict must have pertained to one or both of them (Opp. 16), but Plaintiff has not pointed to a single transcript excerpt, exhibit or filing in which AbbVie disputed any other element of strict liability. *See Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 791-92 (10th Cir. 1997) (inconsistency where "elements of defectiveness and causation were common" and "were essentially the only elements disputed at trial").

other cases in Plaintiff's string cite are distinguishable for similar reasons.[14] Where, as here, the jury reached different results on claims with overlapping elements, the inconsistency is fatal.[15]

B. THE REMEDY FOR THE INCONSISTENCY IS A NEW TRIAL

Plaintiff argues that, even if there is an inconsistency, the Court may strike the inconsistent portion of the verdict. (Opp. 17.) But that is not the remedy for an irreconcilable inconsistency. This Court has itself observed: "If we cannot [reconcile inconsistent verdicts]. . . . the appropriate remedy is a new trial on all claims." *Deloughery* v. *City of Chicago*, 2004 WL 1125897, at *2 (N.D. Ill. May 20, 2004) (Kennelly, J.) (quoting *EEOC* v. *Mid–Continent Security Agency, Inc.*, 2001 WL 800089, at *2 (N.D. Ill. July 12, 2001) (Kennelly, J.)), *aff'd*, 422 F.3d 611 (7th Cir. 2005)).

To support his argument to the contrary, Plaintiff cites *American Casualty Company of Reading, Pennsylvania* v. *B. Cianciolo, Inc.*, 987 F.2d 1302 (7th Cir. 1993), where the jury found

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[14] *See Talkington* v. *Atria Reclamelucifers Fabrieken BV*, 152 F.3d 254 (4th Cir. 1998) (finding claims had distinct elements and turned on different standards); *Sterner* v. *U.S. Plywood-Champion Paper*, 519 F.2d 1352 (8th Cir. 1975) (dated decision under Iowa law contains only cursory statement on inconsistency; instructions not available online; decision prompted concurrence and was later questioned in *Randall* v. *Warnaco*, 677 F.2d 1226, 1232 (8th Cir. 1982), which "recognize[d] that the verdicts in *Sterner* may seem inconsistent and irreconcilable"); *In re Vioxx Prods. Liab. Litig.*, 523 F. Supp. 2d 471 (E.D. La. 2007) (one sentence finding no inconsistency under South Carolina law; MDL filings show negligence claim did not require unreasonable dangerousness); *id.* ECF No. 8673 at 16-17; *Ramirez* v. *E.I. DuPont de Nemours & Co.*, 579 Fed. Appx. 878 (11th Cir. 2014) (addressing distinct argument that verdict was inconsistent because jury found defect but no causation); *State Farm* v. *W.R. Grace & Co.*, 834 F. Supp. 1052 (C.D. Ill. 1993) (negligence claim did not require unreasonable dangerousness); *Densberger* v. *United Tech.*, 125 F. Supp. 2d 585 (D. Conn. 2000) (no inconsistency due to instruction "that [defendant] could be held liable for breaching a post-sale duty to warn on the plaintiffs' negligence theory of liability . . . but not under the plaintiffs' strict liability" theory); *Grant* v. *Westinghouse Elec.*, 877 F. Supp. 806 (E.D.N.Y. 1995) ("'negligent failure to warn' charge would permit the jury to conclude . . . that Westinghouse was negligent *after* the product was released . . . [yet] a failure to warn under a strict products liability scenario . . . necessarily would include a determination that the product was defective when it left the manufacturer's hands."); *Randall*, 677 F.2d 1226 (court, in dicta, found it "conceptually impossible to say that a verdict for the defendant in a strict liability count always disposes of plaintiff's negligence claim based on the same alleged defect, unless one assumes that to be negligent the conduct of the manufacturer must render the product unreasonably dangerous in the strict liability sense"); *Trull* v. *Volkswagen*, 320 F.3d 1 (1st Cir. 2002) (strict liability required defective design yet negligence required *either* negligent design or testing).

[15] *See, e.g.*, *Oja*, 111 F.3d at 791–92 ("Despite the theoretical differences . . . . [T]he elements of defectiveness and causation were common . . . . [And] these two elements were essentially the only elements disputed at trial. To find for [plaintiff] on her negligent failure to warn claim, the jury had to find that the PCA hip was defective at the time of sale and caused her injuries. To find for [defendant] on [plaintiff's] strict liability claim, the jury had to find that the PCA hip was either not defective at the time of sale or did not cause her injuries. Given these parameters, we hold that the verdict for [plaintiff] on her negligent failure to warn claim and the verdict for [defendant] on [plaintiff's] strict liability failure to warn claim were facially inconsistent. Accordingly, we vacate the judgment of the district court and order a new trial.").

that an insured party submitted fraudulent claims but also that the insurance company handled those claims in bad faith. The Court found the verdict reconcilable: "[P]erhaps the insured committed fraud but the insurer did not detect that problem, denying the claims for some other, and illegitimate, reason." *Id.* at 1305. As a *secondary* way to resolve the inconsistency, the Court struck the bad faith finding, not because it was inconsistent, but because it was not supported by the evidence: "A judge may dissipate the inconsistency by setting aside one of the conflicting verdicts, if that verdict was unsupported by the evidence." *Id.* By striking an unsupported finding, the Court rendered the verdict consistent. But the Court did not hold that a court may "cure" an inconsistency by simply throwing out one of the verdicts without actually finding it "was unsupported by the evidence."[16] Instead, the Court observed that "[i]nconsistency produces a new trial."[17]

III.
ALTERNATIVELY, THE COURT SHOULD REDUCE THE PUNITIVE AWARD

For reasons set forth in AbbVie's moving brief and reviewed further below in connection with the reprehensibility requirement,[18] Plaintiff's punitive damages award should be stricken in its entirety, and if not stricken, should be reduced in accordance with clear and dispositive Supreme Court precedents. Plaintiff's opposition ignores the constitutional ratio limitation on punitive damages, comparable civil penalties, and similar limitations under Illinois law. Instead, he spends the bulk of his punitive damages section cherry-picking and misapplying reprehensibility factors.

In attempting to defend the $140,000,000 punitive damages award in this case, which is 1,000x the compensatory award, Plaintiff fails to address the constitutional rule that "few awards exceeding a single-digit ratio" are allowed. *State Farm Mut. Auto. Ins. Co.* v. *Campbell*, 538 U.S.

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16 Nor does Plaintiff concede that any portion of the verdict is unsupported by the evidence such that it could be stricken.

17 AbbVie maintains for purposes of this motion and appeal that a new trial is further warranted due to jury instruction errors, erroneous evidentiary rulings, and because the verdict is against the weight of the evidence. (Mot. 16-22.)

18 Plaintiff's opposition provides no substantive response to the argument in AbbVie's moving brief that Plaintiff failed to present substantial evidence sufficient to support an award of punitive damages. (*Compare* Mot. 12-15, *with* Opp. 15.) AbbVie therefore focuses its response herein on the issue of reprehensibility.

408, 425 (2003).[19] Nor does he address the principle that a 1:1 ratio is appropriate where a compensatory award is substantial and contains a punitive element. *Id.* at 425–26; *Mendez-Matos* v. *Guaynabo*, 557 F.3d 36, 55 (1st Cir. 2009). The $140,000 compensatory award here is substantial and already contains a punitive element in the form of an award for emotional distress.[20] By ignoring AbbVie's argument that the substantial compensatory award and its inclusion of emotional distress requires a 1:1 ratio, Plaintiff has waived any opposition to the argument. *See Wojtas* v. *Capital Guardian Tr. Co.*, 477 F.3d 924, 926 (7th Cir. 2007). Plaintiff's cases regarding a larger permissible ratio are all distinguishable.[21] And Plaintiff's assertion that AbbVie's conduct affected "millions" of other men (Opp. 23) conflicts with the Supreme Court's instructions in *Philip Morris USA* v. *Williams*, 549 U.S. 346 (2007). Under the applicable law in the circumstances present here, any punitive damage award should not exceed the jury's $140,000 compensatory award.

AbbVie also demonstrated in its moving brief that comparable civil penalties require a substantial reduction of the punitive award, and that in addition to federal constitutional limitations, Illinois state law also requires a substantial reduction. (Mot. 24-25.) Plaintiff entirely ignores these points, and makes no attempt to distinguish the numerous authorities cited in support of them.

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[19] *See* Test for excessiveness—Size of verdict—Ratios, 2 Punitive Damages: Law and Prac. 2d § 18:6 (2017 ed.) (collecting cases in which "courts have begun to heed the single-digit multiplier rule"); *Applying constitutional doctrine to the products liability context*, 3 Owen & Davis on Prod. Liab. § 26:42 (4th ed.) ("courts have more closely focused on the ratio of punitive damages to compensatory damages") (collecting cases).

[20] *See, e.g.*, *Mendez-Matos*, 557 F.3d at 55 (finding $35,000 compensatory award "amply" compensated plaintiff for mental distress); *Bains LLC* v. *Arco Prod. Co.*, 405 F.3d 764, 776 (9th Cir. 2005) (finding $50,000 compensatory award "substantial" and remanding for reduction of $5 million punitive award to single-digit ratio); *In re Bayside Prison Litig.*, 331 F. App'x 987, 993 (3d Cir. 2009) (calling $45,000 compensatory award "substantial").

[21] *See TXO Prod. Corp.* v. *All. Res. Corp.*, 509 U.S. 443, 472 (1993) (Scalia, J., concurring in the judgment) (supplying the decisive votes in a case that preceded *State Farm* and noting that the Court's consideration of "potential," as opposed to "actual," harm—a concept not applicable here—meant that the decision only permitted a 10:1 ratio); *Kemp* v. *Am. Tel. & Tel. Co.*, 393 F.3d 1354, 1357, 1363 (11th Cir. 2004) (allowing larger ratio where compensatory award was only $115.05 in light of the Supreme Court's observation that "in some situations a higher ratio may be appropriate where a 'particularly egregious act has resulted in only a small amount of economic damages'") (quoting *State Farm*, 538 U.S. at 425)); *In re Estate of Hoellen*, 854 N.E.2d 774, 779 (Ill. App. Ct. 2006) (allowing larger ratio where only one dollar had been awarded); *Lewellen* v. *Franklin*, 441 S.W.3d 136, 148 (Mo. 2014) (allowing larger ratio in light of "the particularly egregious conduct and the relatively small amount [$25,000] of compensatory damages"); *see also In re Actos (Pioglitazone) Prod. Liab. Litig.*, 2014 WL 5461859, at *55 (W.D. La. Oct. 27, 2014) (although permitting 25:1 ratio, reducing punitive damages award to 1/244th of the jury's award, and settling prior to appeal).

Accordingly, Plaintiff has acquiesced to those arguments. *See Wojtas*, 477 F.3d at 926.

Turning to reprehensibility, two indisputable facts undermine any suggestion that AbbVie's conduct was so reprehensible as to merit an award of punitive damages, much less an award of the extraordinary magnitude at issue here: (1) AbbVie was completely transparent with the FDA, disclosing all available scientific evidence regarding CV risk, its different interpretation of the indication, branded ads (as required under FDA regulations) and even unbranded materials (which were well known to the FDA in any event) (Mot. 13); and (2) still today, science has not established any causal relationship between TRT and increased CV risk, either in the scientific literature or in the eyes of the FDA (Mot. 5–7 n.8). Indeed, the most recent scientific evidence not only shows no increased CV risk, but a potential CV benefit, from TRT use (*E.g.* Tr. 1996:9–1997:7). On these facts, there simply is no basis to find that AbbVie's actions were so reprehensible as to justify this massive punitive damages award. *See, e.g.*, *In re Prempro Prod. Liab. Litig.*, 586 F.3d 547, 571–72 (8th Cir. 2009) (affirming judgment as a matter of law for defendant on punitive damages in part because defendant "did not conceal or restrict the dissemination of [safety] information"); *Hagen* v. *Richardson-Merrell, Inc*., 697 F. Supp. 334, 339–40 (N.D. Ill. 1988) (granting summary judgment for defendant on punitive damages where "the existence of [the alleged risks at issue] had not been demonstrated conclusively"); *Kopczick* v. *Hobart Corp.*, 721 N.E.2d 769, 776, 779 (Ill. App. Ct. 1999) (reversing award of punitive damages where plaintiff could not establish defendant's knowledge of an "unreasonably dangerous" product).

Plaintiff seeks to distract attention from these dispositive facts by emphasizing that he suffered a serious injury. (Opp. 23.) But nearly *every* products liability case involves physical injury, so that alone cannot meaningfully impact the analysis. And in this case, Plaintiff's heart attack fortunately was not fatal, and he quickly recovered.

Plaintiff also argues that AbbVie disregarded safety through age-related marketing, failure to conduct a long-term CV study, and in its labeling. (Opp. 23.) Yet AbbVie received specific

guidance from the FDA on what it could or could not say in its marketing regarding age-related hypogonadism and never crossed the line. The fact that FDA never took action against a single ad speaks volumes. FDA approval may not be dispositive on liability, but it should certainly be on reprehensibility. Nor do allegations of age-related marketing apply to Plaintiff, who was diagnosed with secondary hypogonadism associated with his obesity. *Supra* § C.; *see State Farm*, 538 U.S. at 422–23 (punitive damages may not rest on conduct that bears no relation to plaintiff's harm). With respect to testing and labeling, the FDA deemed the AndroGel safety studies adequate (Trial Exs. 3043.6, 3046.2, 3180.10), and found that its label warned of all known risks (Trial Ex. 3223.6). AbbVie's compliance with the FDA's marketing, testing, and labeling oversight demonstrates that its conduct was not reprehensible.[22] And because Plaintiff's position depends on the notion that AbbVie knew AndroGel was unsafe in July 2010, it bears repeating that to this day, science does not show that AndroGel increases CV risk.

Plaintiff also asserts (without citing the record) that he was "vulnerable," and emphasizes that AbbVie has $5.6 billion in net worth. (Opp. 23-24.) As AbbVie established in its moving brief, however, a company's net worth cannot justify an excessive award. (Mot. 25.) That is particularly so in the MDL context, as AbbVie faces potential liability to thousands of plaintiffs and so under-deterrence because of unlitigated claims is not an issue—a factor recognized under Illinois law that Plaintiff entirely sidesteps.[23] AbbVie also did not evince "intentional malice, trickery, or deceit," nor engage in "repeated" fraud.[24]

CONCLUSION

In sum, AbbVie respectfully requests that the Court vacate the punitive damages award and enter judgment in its favor, or alternatively, grant a new trial or reduce the punitive damages award.

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22 *See, e.g.*, *Prosser and Keeton on Torts*, § 36 at 233 n.41 (5th ed. 1984); *Roginsky* v. *Richardson-Merrell, Inc.*, 378 F.2d 832, 840-41 (2d Cir. 1967) (Friendly, J.) ("A manufacturer distributing a drug to many thousands of users under government regulation scarcely requires" [punitive damages])

23 *See Hazelwood* v. *Illinois Cent. Gulf R.R.*, 450 N.E.2d 1199, 1208 (Ill. App. Ct. 1983).

24 *See Roboserve, Inc.* v. *Kato Kagaku Co.*, 78 F.3d 266, 276 (7th Cir. 1996) ("To justify punitive damages, the allegedly outrageous conduct must 'involv[e] some element of outrage similar to that usually found in a crime.'").

Dated: December 22, 2017

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CERTIFICATE OF SERVICE

I, David Bernick, hereby certify that on December 22, 2017, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ David Bernick
David Bernick